REMARKS

The Office Action mailed September 19, 2006 has been received and reviewed. The application is to be amended as previously set forth. Claims 3 and 4 are to be canceled and claim 27 is to be added. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been entered. Claims 1, 2, and 5-27 are pending in the application. Claims 1-19 stand rejected. Reconsideration is respectfully requested.

1. Claims Rejections and 35 U.S.C. § 102

Claims 1-3 and 5-19 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 4,906,457 (hereinafter "Ryan") in the light of evidence by Pearce *et al.* (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462) (hereinafter "Pearce"). Claim 3 has been canceled herein, thereby mooting that portion of the rejection. Applicants respectfully traverse the rejections.

The subject matter of claim 4 has been incorporated into independent claim 1. Therefore, for at least this reason, claim 1 is not anticipated. Claims 2 and 5-19 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

Claims 1-3 and 5-19 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 3,950,509 (hereinafter "Geks") in the light of evidence by Pearce. Claim 3 has been canceled herein, thereby mooting that portion of the rejection. Applicants respectfully traverse the rejections.

The subject matter of claim 4 has been incorporated into independent claim 1. Therefore, for at least this reason, claim 1 is not anticipated. Claims 2 and 5-19 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

Claims 1, 2, 4-6, 12, and 13 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Rodis *et al.*, ("Naturally occurring protein crystals in the potato." Plant Physiol. 1984, 74:907-911) (hereinafter "Rodis") in the light of evidence by Pearce. Claim 4 has been

canceled herein, thereby mooting that portion of the rejection. Applicants respectfully traverse the rejections.

The subject matter of claim 3 has been incorporated into independent claim 1. Therefore, for at least this reason, claim 1 is not anticipated. Claims 2, 5, 6, 12, and 13 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

2. Claims 1-19 and 35 U.S.C. § 103(a)

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Ryan and Geks taken with Rodis and Pearce. Claims 3 and 4 have been canceled herein, thereby mooting that portion of the rejection. Specifically, it was thought that Ryan and Geks are silent about the pH of compositions with potato inhibitors. It was suggested that Rodis teaches that potato protease inhibitors are readily dissolved at pH 4-5 unlike neutral or alkaline pH. Applicants respectfully traverse the rejections.

Claim 1 as amended recites "the composition having a pH range of about 4.8 to about 5.5." Rodis may not be relied upon to modify the compositions of either Ryan or Geks to have a pH of about 4.8 to about 5.5. Just because the potato protease inhibitors of Rodis dissolved at pH 4-5 does not mean that it would be desirable for compositions of Ryan and Geks to have a pH of 4-5. On the contrary, different protease inhibitors function better at different pH's. The specification of the present application discloses that pepsin from the stomach works optimal at pH 2 and trypsin, chymotrypsine, and elastase work optimal at pH 7-8. *Specification, paragraph [0004].* Ryan discloses that chymostrypsin and trypsine are preferred plant derived serine protease inhibitors. *Col. 1, line 67 to Col. 2, line 2.* Ryan also discloses that elastase inhibitors are appropriate. *Col. 2, lines 6-8.* Thus, attempting to modify the composition of Ryan to have a pH of about 4.8 to about 5.5 may render the invention of Ryan unsuitable for its intended purpose. *See M.P.E.P. § 2143.01.* Likewise, Geks discloses kallikren-trypsin inhibitors. *Office Action mailed September 19, 2006, page 4.* It cannot be assumed that kallikren-trypsin inhibitors are effective at a pH of about 4.8 to about 5.5. Additionally, Geks teaches away from acidic deodorants. Geks discloses that strong acidic solutions can cause damage to clothing and sensitive fabrics. *Col. 1, lines 56-57.* Thus, attempting to modify the deodorants of Geks to have

a pH of about 4.8 to about 5.5 may render the invention of Geks unsuitable for its intended purpose. *See M.P.E.P. § 2143.01.*

Additionally, claim 1 as amended recites "the inhibitors comprising from 1 to 20 wt.%, based on the total weight of the composition." The Office acknowledged that Rodis does not teach this subject matter. *Office Action mailed September 19, 2006, page 4.* Likewise, neither Ryan nor Geks teach or suggest this subject matter. Ryan discloses a preferred concentration of 0.1 mg of inhibitor per mL of topical mixture. Ryan discloses a range of 10 picograms to 10 mg of inhibitor per mL of topical mixture. At the maximum of the range disclosed in Ryan, if the topical mixture has the density of water (*e.g.*, 1000 mg/mL), then 10 mg of inhibitor equals almost 1 wt.% of the topical mixture (*i.e.*, 0.99 wt.%). However, Ryan does not disclose a topical mixture of only water and protease inhibitor. The simplest example in Ryan includes water, glycol, and a protease inhibitor. Glycol has a density greater than water (approximately 1126 mg/mL). Thus, the maximum of 10 mg of inhibitor disclosed in Ryan, does not even equal 1 wt.% of the topical mixture. In that example, the 5 mg of inhibitor equals about 0.01 wt.%. Thus, 10 mg of inhibitor would only equal about 0.02 wt.%. Additionally, because the ranges and examples of Ryan disclose the use of much smaller quantities of inhibitors, one of skill in the art would not extrapolate, based upon the disclosure of Ryan, that the claimed inhibitor ranges would be a viable option. Therefore, Ryan does not teach or suggest inhibitors comprising from 1 to 20 wt.%.

Geks discloses a range of potato inhibitors from 1.5 wt.% to about 3 wt.%. *Office Action mailed September 19, 2006, page 4.* One of skill in the art would not extrapolate 1.5 – 3 wt.% to teach or suggest 1 to 20 wt.%. Therefore, Geks does not teach or suggest inhibitors comprising from 1 to 20 wt.%.

For at least the above reasons, Ryan and Geks may not be modified by Rodis to teach claim 1 as amended. Claims 2 and 5-19 are non-obvious for at least the reason of depending from claim 1. Therefore, applicants respectfully request withdrawal of the rejections.

3. Claim 27

Applicants also submit that new claim 27 is novel and non-obvious over the cited references. None of the cited references teach or suggest a skin care or topical pharmaceutical

composition for the alleviation of inflammation caused by proteolytic activity of feces. Support for new claim 27 may be found throughout the as-filed specification, such as in paragraph [0014]. Applicants submit that claim 27 reads on the elected claims and, thus, should be considered by the Office.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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